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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,016	12/29/2003	Vincent P. Bavaro	ACS 66062 (4045X)	6513

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FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER

BRUENJES, CHRISTOPHER P

ART UNIT PAPER NUMBER

1772

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,016

Applicant(s)

BAVARO ET AL.

Examiner

Christopher P. Bruenjes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b):

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 24-40 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 24-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 20031229, 20050518, 20050718.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-5 and 24-40 in the reply filed on September 6, 2006 is acknowledged.

2. Claims 6-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 6, 2006.

Specification

3. The use of the trademarks PEBAX, PELLETHANE, HYTREL, SANTOPRENE, KRATON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. For more information see MPEP 608.01(v).

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Claim Rejections - 35 USC § 112

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation of claim 29 that the radiopaque marker further comprises a coating is not supported by the original specification. The specification teaches adding a coating layer over a guide wire or medical device in which a marker is attached, but there is no support for the marker itself to be coated with a separate coating layer.

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6. The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3, 28-29, 36, 37, and 39-40 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3, the limitation "Pebax" renders the claim vague and indefinite because it is a trade name or trademark, which cannot be used properly to identify any particular material or product. See MPEP 2173.05(u).

Regarding claims 28 and 39-40, the limitation that the radiopaque marker "forms an extrusion coating" or "exterior coating" renders the claim vague and indefinite because it is not understood how a marker forms a coating. Is the marker a coating? Is the composition extruded to form a marker, which is a coating? Clarification is required.

Regarding claim 29, the limitation "further comprising a coating" renders the claim vague and indefinite because it is not understood if the marker is a coating or if the marker has a coating layer on the outer surface of the marker.

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Regarding claims 36-37, the limitation "the wetting agent" lacks antecedent basis. It appears the wetting agent is referring to the agent facilitating adhesion in claim 32.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-4, 24-26, 28, 30-37, and 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Elliott (US 2003/0164063 A1).

Regarding claims 1-4, 25-26, 32-34, 36-37, the preamble "radiopaque marker" is given little patentable weight for two reasons. First, it appears the preamble is reciting purpose or intended use of the claimed article, which would only be given weight with regard to any structural difference the intended use results in. Second, if the preamble is not merely reciting purpose or intended use the only structural limitation provided

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by "radiopaque marker" is an article that is opaque to radiation, such as x-rays. This limitation would cover any article as long as it is opaque to radiation. The article of Elliott is a radiation-shielding article (p.3, paragraph 56) and therefore anticipates the structural limitations provided by the preamble. The article of Elliott comprises a polymer such as Pebax and radiopaque particles such as tungsten disposed within said polymer and a wetting agent for facilitating encapsulation of said particles such as a surfactant provided by a wax and a fluoropolymer and/or a coupling agent such as chemically modified polyethylene (p.5, paragraphs 88-93 and Table 2 on p.6). The tungsten has an average diameter of at least 2 microns and a maximum diameter of about 20 microns, as shown by the particle size distribution (p.6, paragraph 94). The radiopaque particles include greater 93.9 weight percent of the composite (Table 2 on page 6).

Regarding claims 24 and 35, the radiopaque particles are substantially equiaxed as shown by the particle size distribution (p.6, paragraph 94).

Regarding claims 28-31, 39, and 40, the limitations that the marker is a coating or attached to a medical device are intended use functional limitations of the radiopaque marker. The marker is an article and articles are defined by there

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structure not merely what the article is used for or how it is made. The functional limitations of these claims do not add further structural limitations to the marker, so they are given little patentable weight. The composite of Elliott has the ability to be used in the forms claimed, therefore the composite anticipates the claim. See MPEP 2114.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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12. Claims 5, 27, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott (US 2003/0164063 A1).

Regarding claim 5, Elliott teaches all that is claimed in claim 1 as shown above, and teaches that the article is manufactured as a radiation shield. Elliott fails to teach that the article is necessarily formed to define a tubular structure. However, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that depending on the shape of the object the article of Elliott is providing a radiation shield to would determine the shape of the article of Elliott.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the radiation shield of Elliott to define a tubular structure when the object shielded from radiation has a tubular shape.

Regarding claims 27 and 38, Elliott teaches all that is claimed in claims 1 and 32 as shown above, but fail to teach that the article further comprises an antioxidant. However, it is well known in the art that antioxidants are added to elastomers in order to improve prevent oxidative decomposing, and therefore have longer stability and life. Therefore, it would have been obvious to one having ordinary skill in the art

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to add an antioxidant to an article formed of Pebax in order to increase the stability and life of the article, since antioxidants prevent oxidation and decomposition caused by oxidation.

Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add an antioxidant to the article of Elliott, since it is well known in the art as a common additive to elastomers and would be added in order to prevent premature oxidation of the article.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Klein et al (USPN 5,776,141) teaches a similar radiopaque marker but fails to teach diameter of the radiopaque particles and a wetting agent. Also cited are: McMahon (USPN 6,994,723); Stoltze et al (USPN 6,059,738); Chiu et al (USPN 6,761,708); Boylan et al (US 2001/0049549 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB
October 28, 2006



ALICIA CHEVALIER
PRIMARY EXAMINER